REMARKS

Reconsideration and allowance in view of the foregoing amendments and the following remarks are respectfully requested.

Upon entry of this Amendment, claims 1-24 and 27-66 will be pending in the present application. No claims have been newly added. Claims 25 and 26 have been cancelled. Claims 1-4, 9, 15, 27, 28, 30, 31, 36-38, 40, 41, 61, and 62 have been amended.

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The specification has been objected to for including trademarks [the Office Action, p. 2]. In particular, the Examiner alleges that the specification includes trademarks that are not capitalized and accompanied by the appropriate generic terminology [*id.*]. Applicant traverses this objection on the grounds that all of the trademarks present in the specification are capitalized, identified as registered marks, and accompanied by the appropriate generic language. For example, the specification discusses "the BiPAP® family of devices," "the REMstar® and Solo® family of CPAP devices," "the Virtuoso® CPAP family of devices," and "the Tranquility® Auto CPAP device" [¶¶ 3-5]. Accordingly, this objection should be withdrawn.

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Claims 15 and 42-66 currently stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite [the Office Action, p. 3]. Applicant respectfully submits that the above amendment to the claims correct the specific formalities objected to by the Examiner as discussed in detail below.

Claim 15

With respect to claim 15, the Examiner alleges that the terms "static period," "rotating period," and "dynamic period" are indefinite [*id.*]. Without acknowledging the propriety of this rejection, Applicant has amended claim 15 to address the Examiner's objections. Based on the amendment to claim 15 above, this rejection is believed to be moot.

Claims 42-60

With respect to claim 42, the Examiner alleges that the specification does not disclose structure, material, or acts that correspond to the functions attributed to the "means for monitoring," and the "processing means" recited in claim 42 [*id.*]. Applicant traverses this rejection on the grounds that the specification as originally filed provides support for each of these recitations that would enable one of ordinary skill in the art to determine the scope of claim 42.

For example, regarding the recitation of "processing means for determining a compliance period value...," the specification states that controller 28, communication device 32, and/or computing device 34 illustrated in FIG. 2 may be configured to perform the compliance monitoring algorithm disclosed in the specification [*see, e.g.*, ¶¶ 63-64]. The compliance monitoring algorithm disclosed in the specification may include "determining the compliance period value..." as recited in claim 42 [*see, e.g.*, ¶ 20]. As such, the "processing means for determining a compliance period value..." at least may include one or more of controller 28, communication device 32, and/or computing device 34 described in the specification and shown in FIG. 2.

Regarding the "means for monitoring an actual medical device usage," FIG. 2 illustrates a flow meter 20 and pressure meter 26 connected to controller 28. The specification discloses that these elements may be used to perform portions of the compliance monitoring algorithm, such as monitoring an actual medical device usage [*see, e.g.*, ¶ 44]. Further, in embodiments in which the "processing means" is implemented in computing device 34, the means for obtaining the actual medical device usage (*i.e.*, "monitoring an actual medical device usage") may be communication device 32 [*see, e.g.*, ¶ 46]. As such, the "means for monitoring..." recited in claim 42 at least may include one or more of flow meter 20, pressure meter 26, controller 28, and/or communication device 32.

Therefore, the recitations of means-plus-function in claim 42 are supported by the specification and drawings as originally filed. For at least this reason the rejection of claim 42 (and its dependent claims 43-60) under 35 U.S.C. § 112, second paragraph, as allegedly being unclear should be withdrawn.

Claim 61

With respect to claim 61, the Office Action alleges that the specification does not disclose structure, material, or acts that correspond to the functions attributed to the "means for monitoring," and the "processing means" recited in claim 61 [p. 3]. Applicant traverses this rejection on the grounds that the specification as originally filed provides support for each of these recitations that would enable one of ordinary skill in the art to determine the scope of claim 61.

Regarding the recitation of "processing means for (1) comparing the actual medical device usage value for each medical device usage session with the minimum medical device usage short session value and (2) determining an actual medical device usage value for the compliance period by summing the actual medical device usage value for each medical device usage session during the compliance period that is greater than or equal to the minimum medical device usage short session value and excluding from the sum the actual medical device usage values for medical device usage sessions during the compliance period that are less than the minimum medical device usage short session value," the specification states that controller 28, communication device 32, and/or computing device 34 illustrated in FIG. 2 may be configured to perform the compliance monitoring algorithm disclosed in the specification [*see, e.g.*, ¶¶ 63-64]. The compliance monitoring algorithm disclosed in the specification may include "(1) comparing the actual medical device usage value for each medical device usage session with the minimum medical device usage short session value and (2) determining an actual medical device usage value for the compliance period by summing the actual medical device usage value for each medical device usage session during the compliance period that is greater than or equal to the minimum medical device usage short session value and excluding from the sum the actual medical device usage values for medical device usage sessions during the compliance period that are less than the minimum medical device usage short session value" [*see, e.g.*, ¶ 48]. As such, the "processing means ..." at least may include one or more of controller 28, communication device 32, and/or computing device 34 described in the specification and shown in FIG. 2.

Regarding the "means for monitoring an actual medical device usage for at least one discrete medical device usage session," FIG. 2 illustrates a flow meter 20 and pressure meter

26 connected to controller 28. The specification discloses that these elements may be used to perform portions of the compliance monitoring algorithm, such as monitoring an actual medical device usage [*see, e.g.*, ¶ 44]. Further, in embodiments in which the "processing means" is implemented in computing device 34, the means for obtaining the actual medical device usage (*i.e.*, "monitoring an actual medical device usage for at least one discrete medical device usage session") may be communication device 32 [*see, e.g.*, ¶ 46]. As such, the "means for monitoring..." recited in claim 61 at least may include one or more of flow meter 20, pressure meter 26, controller 28, and/or communication device 32.

Therefore, the recitations of means-plus-function in claim 61 are supported by the specification and drawings as originally filed. For at least this reason the rejection of claim 61 under 35 U.S.C. § 112, second paragraph, as allegedly being unclear should be withdrawn.

Claim 62

With respect to claim 62, the Office Action alleges that the specification does not disclose structure, material, or acts that correspond to the functions attributed to the "means for monitoring," and the "processing means" recited in claim 62 [p. 3]. Applicant traverses this rejection on the grounds that the specification as originally filed provides support for each of these recitations that would enable one of ordinary skill in the art to determine the scope of claim 62.

Regarding the recitation of "processing means for (1) applying a weighting factor to each actual medical device session usage value to produce a weighted actual medical device session usage value for each medical device usage session, and (2) determining an actual medical device usage value for the compliance period by summing the weighted actual medical device usage values for the medical device usage sessions during the compliance period," the specification states that controller 28, communication device 32, and/or computing device 34 illustrated in FIG. 2 may be configured to perform the compliance monitoring algorithm disclosed in the specification [*see, e.g.*, ¶¶ 63-64]. The compliance monitoring algorithm disclosed in the specification may include "(1) applying a weighting factor to each actual medical device session usage value to produce a weighted actual medical device session usage value for each medical device usage session, and (2) determining an actual medical device usage

value for the compliance period by summing the weighted actual medical device usage values for the medical device usage sessions during the compliance period" [*see, e.g.*, ¶¶ 49-50]. As such, the "processing means ..." at least may include one or more of controller 28, communication device 32, and/or computing device 34 described in the specification and shown in FIG. 2.

Regarding the "means for monitoring an actual medical device usage for at least one discrete medical device usage session," FIG. 2 illustrates a flow meter 20 and pressure meter 26 connected to controller 28. The specification discloses that these elements may be used to perform portions of the compliance monitoring algorithm, such as monitoring an actual medical device usage [*see, e.g.*, ¶ 44]. Further, in embodiments in which the "processing means" is implemented in computing device 34, the means for obtaining the actual medical device usage (*i.e.*, "monitoring an actual medical device usage for at least one discrete medical device usage session") may be communication device 32 [*see, e.g.*, ¶ 46]. As such, the "means for monitoring..." recited in claim 62 may at least include one or more of flow meter 20, pressure meter 26, controller 28, and/or communication device 32.

Therefore, the recitations of means-plus-function in claim 62 are supported by the specification and drawings as originally filed. For at least this reason the rejection of claim 62 (and its dependent claims 63 and 64) under 35 U.S.C. § 112, second paragraph, as allegedly being unclear should be withdrawn.

Claim 65

With respect to claim 65, the Office Action alleges that the specification does not disclose structure, material, or acts that correspond to the functions attributed to the "means for monitoring," and the "processing means" recited in claim 65 [p. 3]. Applicant traverses this rejection on the grounds that the specification as originally filed provides support for each of these recitations that would enable one of ordinary skill in the art to determine the scope of claim 65.

Regarding the recitation of "processing means for (1) comparing the actual medical device usage value for a discrete usage session with a minimum medical device usage short session value, and (2) determining a short session count value based upon the number of

usage sessions where the actual medical device usage value for the respective usage session is less than the minimum medical device usage short session value," the specification states that controller 28, communication device 32, and/or computing device 34 illustrated in FIG. 2 may be configured to perform the compliance monitoring algorithm disclosed in the specification [*see, e.g.*, ¶¶ 63-64]. The compliance monitoring algorithm disclosed in the specification may include "(1) comparing the actual medical device usage value for a discrete usage session with a minimum medical device usage short session value, and (2) determining a short session count value based upon the number of usage sessions where the actual medical device usage value for the respective usage session is less than the minimum medical device usage short session value" [*see, e.g.*, ¶ 56]. As such, the "processing means ..." at least may include one or more of controller 28, communication device 32, and/or computing device 34 described in the specification and shown in FIG. 2.

Regarding the "means for monitoring an actual medical device usage for at least one discrete medical device usage session," FIG. 2 illustrates a flow meter 20 and pressure meter 26 connected to controller 28. The specification discloses that these elements may be used to perform portions of the compliance monitoring algorithm, such as monitoring an actual medical device usage [*see, e.g.*, ¶ 44]. Further, in embodiments in which the "processing means" is implemented in computing device 34, the means for obtaining the actual medical device usage (*i.e.*, "monitoring an actual medical device usage for at least one discrete medical device usage session") may be communication device 32 [*see, e.g.*, ¶ 46]. As such, the "means for monitoring..." recited in claim 65 at least may include one or more of flow meter 20, pressure meter 26, controller 28, and/or communication device 32.

Therefore, the recitations of means-plus-function in claim 65 are supported by the specification and drawings as originally filed. For at least this reason the rejection of claim 65 (and its dependent claim 66) under 35 U.S.C. § 112, second paragraph, as allegedly being unclear should be withdrawn.

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Claims 36-41 currently stand rejected under 35 U.S.C. § 101 for allegedly reciting non-statutory subject matter [the Office Action, p. 4]. In particular, the Examiner alleges that claims 36-41 recite methods that are (1) not tied to a machine, and (2) do not transform underlying subject matter to a different state or thing. While Applicant disagrees with the propriety of the rejection of claims 36-41 under 35 U.S.C. § 101, Applicant has amended independent claims 36, 37, and 40 to obviate this rejection. In light of the amendments to claims 36, 37, and 40 above, this rejection is believed to be moot.

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Claims 42, 43, and 53 currently stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,706,801 to Remes *et al.* ("the '801 patent") [the Office Action, pp. 4-5]. Applicant respectfully traverses this rejection for the reasons presented below.

The rejection of claims 42, 43, and 53 based on the cited sections of the '801 patent should be withdrawn because the Examiner has failed to demonstrate that the '801 patent clearly and unambiguously discloses each and every feature of the claimed invention. For example, independent claim 42 recites *inter alia* the following features, which are not disclosed in the sections of the '801 patent relied on in the Office Action:

> ...processing means for determining a compliance period value as a number of compliance periods in a measurement cycle in which the actual medical device usage value is at least equal to a minimum medical device usage compliance value.

The Examiner alleges that the '801 patent discloses this feature at column 6, lines 9-11 [the Office Action, p. 5]. This portion of the '801 patent reads as follows:

> The patient must take a given flow rate of sufficiently oxygen-enriched air for a given period of time each day. Based upon the seriousness of the patient's medical conditions, variations from the oxygen prescriptions are allowed. To determine whether a patient is in compliance with prescribed uses, the database program compares the patient's actual use of the concentrator with the allowed variation of his prescription [c. 6, ll. 5-12].

This section of the '801 patent discloses that although a patient is prescribed a treatment regime of taking oxygen-enriched air at a specified flow rate for a specified period of

time, a database program stores allowed variations from this regime. There is no disclosure that such allowed variations are relevant to "determining... a number of compliance periods in a measurement cycle in which the actual medical device usage value is at least equal to a minimum medical device usage compliance value." It seems that the "allowed variations" disclosed in the relied upon portion of the '801 patent, at best, enable a patent to vary the flow rate or the given period of time for a single day. The variation of either of these parameters does not anticipate "determining... a number of compliance periods in a measurement cycle in which the actual medical device usage value is at least equal to a minimum medical device usage compliance value." In fact, the cited section of the '801 patent does not disclose any sort of counting or numbering functionality. Therefore, the Examiner has failed to demonstrate that the cited sections of the '801 patent disclose the features of claim 42 reproduced above.

For the reasons presented above, applicant respectfully submits that independent claim 42 is not anticipated or rendered obvious by the cited references. In addition, claims 43 and 53 are also not anticipated due to their dependency from independent claim 42. Accordingly, Applicant respectfully requests that the above rejection of claims 42, 43, and 53 be withdrawn.

It should be noted that the applicant has not addressed each rejection of the dependent claims. Any rejection of a dependent claim not specifically addressed is not to be construed as an admission by the application of the correctness of that rejection. Rather, the Applicant believes that the independent claims are patentably distinguishable over the cited references for the reasons noted above, so that the rejection of the dependent claims need not be addressed at this time. Applicant reserves the right to address the rejection of any dependent claim at a later time should that become warranted.

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Claims 1-6, 9, 11-16, 25, 26, 30, 31, 33-36, 40, and 41 currently stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 6,249,717 to Nicholson *et al.* ("the '717 patent") in view of Kribbs *et al.*, "Objective Measurement Of Patterns Of Nasal CPAP Use By Patients With Obstructive Sleep Apnea" ("Kribbs"); claims 7, 8, 22-24, 45-48, 60, and 66 currently stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over the '717 patent in view of Kribbs, and in further view of the '801 patent;

claims 49, 51, 52, 54, and 55 currently stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over the '801 patent in view of the '717 patent; claims 10, 17, 18, and 32 currently stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over the '717 patent in view of Kribbs, and in further view of U.S. Patent No. 5,284,133 to Burns *et al.* ("the '133 patent"); claim 19 currently stands rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over the '717 patent in view of Kribbs, in further view of the '133 patent, and in further view of U.S. Patent No. 5,517,983 to Deighan *et al.* ("the '983 patent"); claims 20 and 21 currently stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over the '717 patent in view of Kribbs, and in further view of the '983 patent; claims 27 and 28 currently stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over the '717 patent in view of Kribbs, and in further view of U.S. Patent No. 6,578,003 to Camarda *et al.* ("the '003 patent"); claim 29 currently stands rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over the '717 patent in view of Kribbs, in further view of the '003 patent, and in still further view of U.S. Patent No. 5,359,513 to Kano *et al.* ("the '513 patent"); claims 37 and 38 currently stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over the '717 patent in view of the '003 patent; claim 39 currently stands rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over the '717 patent in view of the '003 patent, and in further view of the '513 patent; claims 44, 59, 61, and 65 currently stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over the '801 patent in view of Kribbs; claim 50 currently stands rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over the '801 patent in view of the '133 patent; claims 56 and 57 currently stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over the '801 patent in view of the '003 patent; claims 62 and 63 currently stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over the '801 patent in view of the '003 patent, and in further view of the '717 patent; and claim 64 currently stands rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over the '801 patent in view of the '003 patent, in further view of the '717 patent, and in still further view of the '513 patent. Applicant respectfully traverses these rejections for the reasons presented below.

Claims 1-24 and 27-35

Without acknowledging the propriety of the rejections of claims 1-24 and 27-35 under 35 U.S.C. § 103, Applicant has amended the claims to further clarify the claimed invention. The rejections of 1-24 and 27-35 should be withdrawn at least because the proposed combinations of the '717 patent, Kribbs, the '801 patent, the '133 patent, the '983 patent, the '003 patent, and/or the '513 patent do not teach or suggest all of the features of these claims, as amended.

For example, claim 1 has been amended to recite *inter alia* the following features, which are not taught by the portions of the '717 patent and/or Kribbs relied on in the Office Action:

> ...weighting, via the computing device, the measurements of medical device usage of the medical device for individual usage sessions during the measurement cycle according to a predetermined weighting scheme....

The Examiner contends that the cited sections of the '717 patent and/or Kribbs teach various aspects of analyzing measurements of therapy administered to a patient. However, these portions of the '717 patent and Kribbs, alone or in combination, do not teach or suggest the weighting of measurements of therapy that has been administered to a patient. As such, the cited sections of the '717 patent and/or Kribbs do not teach or suggest the features of claim 1 reproduced above. The portions of the '801 patent, the '133 patent, the '983 patent, the '003 patent, and/or the '513 patent do not address this deficiency of the '717 patent and Kribbs.

For the reasons presented above, Applicant respectfully submits that independent claim 1 is not rendered obvious by the cited references. In addition, claims 2-24 and 27-35 are also not rendered obvious due to their dependency from independent claim 1. Accordingly, applicant respectfully requests that the above rejection of claims 1-24 and 27-35 be withdrawn.

It should be noted that the applicant has not addressed each rejection of the dependent claims. Any rejection of a dependent claim not specifically addressed is not to be construed as an admission by the application of the correctness of that rejection. Rather, the applicant believes that the independent claims are patentably distinguishable over the cited references for the reasons noted above, so that the rejection of the dependent claims need not be

addressed at this time. Applicant reserves the right to address the rejection of any dependent claim at a later time should that become warranted.

Claim 36

The rejection of claim 36 based on the proposed combination of the '717 patent and Kribbs should be withdrawn at least because the Examiner has not demonstrated that the cited references teach or suggest all of the features of the claimed invention.

For example, claim 36 recites *inter alia* the following features which are not taught or suggested by the sections of the '717 patent and/or Kribbs relied on in the Office Action:

> ...determining a medical device usage value for the compliance period by summing the measurements of medical device usage for each medical device usage session that is greater than or equal to the minimum medical device usage short session value and excluding from the sum each measurement of medical device usage during a medical device usage session during the compliance period that is less than the minimum medical device usage short session value.

The Examiner acknowledges that the '717 patent does not teach the features of claim 36 reproduced above[pp. 12-13]. The Examiner alleges that Kribbs addresses this deficiency of the '717 patent at FIG. 3 and page 889 [*id.*]. In particular, the Examiner alleges that in FIG. 3 (reproduced below), the "black squares" shown teach the "the measurements of medical device usage for each medical device usage session that is greater than or equal to the minimum medical device usage short session value," and that the "blank areas" shown teach "measurement of actual medical device usage value during a medical device usage session during the compliance period that is less than the minimum medical device usage short session value" [p. 13]. Even if this application of Kribbs to the claimed features of claim 36 is accepted (Applicant contends that this interpretation of Kribbs is erroneous), the cited sections of Kribbs still do not teach the features of claim 36 reproduced above.

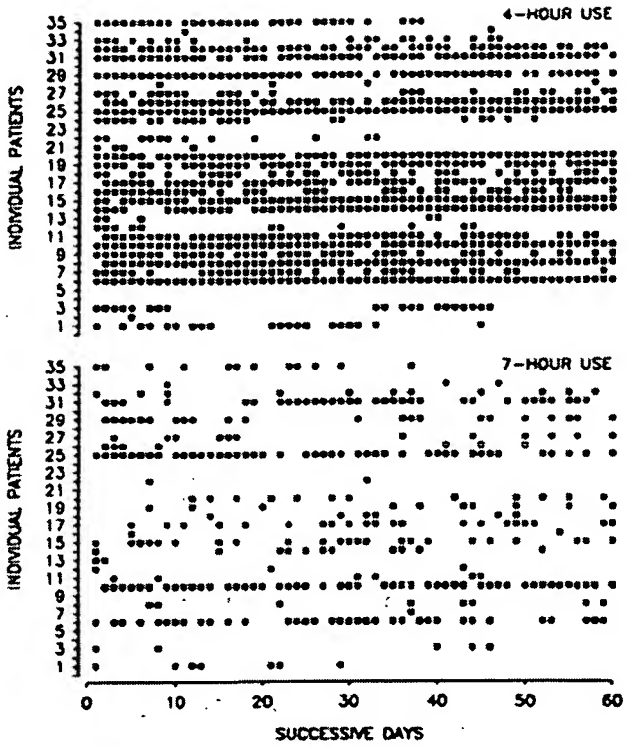

Figure 3. Pattern of day-to-day CPAP use for each of the 35 patients for as many as 60 days, plotted according to two duration of use criteria. The black squares are days when CPAP was used for at least 4 h (*upper panel*) or for at least 7 h (*lower panel*). Blank areas between the squares represent days when CPAP either was not used or not used long enough to meet this duration of use criterion.

At most, FIG. 3 shows that "the measurements of medical device usage for each medical device usage session that is greater than or equal to the minimum medical device usage short session value" and the "measurement of medical device usage during a medical device usage session during the compliance period that is less than the minimum medical device usage short session value" are recorded. There is no teaching of "determining a medical device usage value for the compliance period by summing" the "black squares" and excluding the "blank areas" from the sum, as is required by claim 36 if the "black squares" and the "blank areas" are applied to the recitations of claim 36 in the manner proposed by the Examiner. Therefore, the Examiner has failed to demonstrate that the '717 patent and Kribbs teach or suggest the features of claim 36 reproduced above.

For the reasons presented above, Applicant respectfully submits that independent claim 36 is not rendered obvious by the cited references. Accordingly, Applicant respectfully requests that the above rejection of claim 36 be withdrawn.

Claims 37-39

The rejections of claims 37-39 based on the proposed combinations of the '717 patent, the '003 patent, and/or the '513 patent should be withdrawn at least because the Examiner has not demonstrated that the cited references teach or suggest all of the features of the claimed invention.

For example, claim 37 recites *inter alia* the following features which are not taught or suggested by the sections of the '717 patent and/or the '003 patent relied on in the Office Action:

> ...(b) applying, via the computing device, a weighting factor to the measurements of actual device usage during each of the usage sessions to produce a weighted actual medical device session usage value for each medical device usage session; and
>
> (c) determining, via the computing device, an actual medical device usage value for the compliance period by summing the weighted actual medical device usage values for the medical device usage sessions during the compliance period.

The features of claim 37 reproduced above are the result of the inventors of the present application recognizing "that even short Usage Sessions may have some therapeutic value. However, the shorter the Usage Session, the greater the reduction in the beneficial effect of the medical device. For example, while patient 10 may not get the maximum therapeutic effect from medical device 12 if only used for a 40-minute session, he or she will get an even further reduced therapeutic effect for a 20-minute session." The features of claim 37 reproduced above recite a novel technique for quantifying compliance with a treatment regime using a medical device that accounts for the impact of usage session length on the therapeutic effectiveness of the treatment over a plurality of usage sessions. The Examiner has failed to demonstrate that the cited references teach or suggest adjusting a quantification of past compliance for this effect in the manner recited in claim 37.

The Examiner acknowledges that the '717 patent does not teach or suggest these features [the Office Action, pp. 26-27]. The Examiner alleges that the '003 patent teaches these features at column 12, lines 43-47. In pertinent part, the '003 patent reads as follows:

> Preferably the predictive model is based on the results of logistic regression analysis. Logistic regression utilizes a regression model for binary (dichotomous) outcomes, and the data are assumed to follow binomial distributions with probabilities that depend on the independent variables. The probability equation is computed according to
>
> $$P = \frac{e^{\log it}}{(1+it)};$$
>
> where P is the probability that a given patient will be compliant, e is a constant representing the base of natural logarithms, and log*it* is the sum of (I) a predetermined constant or weight and (ii) each of the high relevance variables multiplied by its respective coefficient. In other words, for n variables v used in the predictive model, the log*it* is computed as follows:
>
> $$\log ic = (c_1 * v_1) + (c_2 * v_2) + (c_3 + v_3) + \ldots + (c_n + v_n) + constnt$$
>
> where c_1 is the coefficient corresponding to variable v_1, c_2 is the coefficient corresponding to variable v_2, etc. The coefficients are preferably logistic regression coefficients or weights which indicate the relative significance of the variable in predicting compliance in response to a particular intervention [c. 12, ll. 25-47 (emphasis added)].

Although this passage from the '003 patent teaches determining weighted coefficients in an equation, the equation is designed to predict "the probability that a given patient will be compliant [in the future]," not "an actual medical device usage value" that quantifies the actual compliance of the patient during a time-period that is already past. Further, the weighted coefficients are designed to provide different weights to different variables based on their impact on the likelihood of future compliance, not adjust the value of past usage sessions in a determination of past compliance to account for the therapeutic value of different usage sessions that have already transpired. As such, the section of the '003 patent cited by the Examiner fails to address the acknowledged deficiency of the '717 patent with respect to the features of claim 37 reproduced above.

For the reasons presented above, applicant respectfully submits that independent claim 37 is not rendered obvious by the cited references. The sections of the '513 patent cited in the Office Action do not address the deficiencies of the '717 patent and the '003 patent set forth

above. As such, claims 38 and 39 are also not rendered obvious due to their dependency from independent claim 37. Accordingly, applicant respectfully requests that the above rejections of claims 37-39 be withdrawn.

It should be noted that the applicant has not addressed each rejection of the dependent claims. Any rejection of a dependent claim not specifically addressed is not to be construed as an admission by the application of the correctness of that rejection. Rather, the applicant believes that the independent claims are patentably distinguishable over the cited references for the reasons noted above, so that the rejection of the dependent claims need not be addressed at this time. Applicant reserves the right to address the rejection of any dependent claim at a later time should that become warranted.

Claims 40 and 41

The rejection of claims 40 and 41 based on the proposed combination of the '717 patent and Kribbs should be withdrawn at least because the Examiner has not demonstrated that the cited references teach or suggest all of the features of the claimed invention.

For example, independent claim 40 recites *inter alia* the following features which are not taught or suggested by the sections of the '717 patent and/or Kribbs relied on in the Office Action:

> ...determining a short session count value based upon the number of usage sessions wherein the measurement of medical device usage for the respective usage session is less than the minimum medical device usage short session value.

The Examiner acknowledges that the '717 patent does not teach the features of claim 40 reproduced above[pp. 12-13]. The Examiner alleges that Kribbs addresses this deficiency of the '717 patent at FIG. 3 and page 889 [*id.*]. In particular, the Examiner relies on the illustration of the "black squares" and the "blank areas" in FIG. 3 as teaching determining "usage sessions wherein the measurement of medical device usage for the respective usage session is less than the minimum medical device usage short session value" [*id.*]. However, even if the "blank areas" shown in FIG. 3 correspond to the "usage sessions wherein the measurement of medical device usage for the respective usage session is less than the minimum medical

device usage short session value" (Applicant contends they do not), the cited portions of Kribbs do not address the admitted deficiency of the '717 patent.

At best, FIG. 3 shows that "usage sessions wherein the measurement of medical device usage for the respective usage session is less than the minimum medical device usage short session value" are identified. There is no teaching of "determining a short session count value based upon the number of" the "blank areas," as is required by claim 40 if Kribb is applied to the recitations of claim 40 in the manner proposed by the Examiner. Therefore, the Examiner has failed to demonstrate that the '717 patent and Kribbs teach or suggest the features of claim 40 reproduced above.

For the reasons presented above, applicant respectfully submits that independent claim 40 is not rendered obvious by the cited references. In addition, claim 41 is also not rendered obvious due to its dependency from independent claim 40. Accordingly, applicant respectfully requests that the above rejection of claims 40 and 41 be withdrawn.

It should be noted that the applicant has not addressed each rejection of the dependent claims. Any rejection of a dependent claim not specifically addressed is not to be construed as an admission by the application of the correctness of that rejection. Rather, the applicant believes that the independent claims are patentably distinguishable over the cited references for the reasons noted above, so that the rejection of the dependent claims need not be addressed at this time. Applicant reserves the right to address the rejection of any dependent claim at a later time should that become warranted.

Claims 44-52 and 54-60

Claims 44-52 and 54-60 depend from (directly or indirectly) independent claim 42. The sections of the '717 patent, Kribbs, the '133 patent, and/or the '003 patent in rejecting claims 44-52 and 54-60 in combination with the '801 patent do not address the deficiencies of the '801 patent with respect to independent claim 42 set forth above. Therefore, the rejections of claims 44-52 and 54-60 based on the proposed combinations of the '801 patent with the '717 patent, Kribbs, the '133 patent, and/or the '003 patent should be withdrawn due to the dependency of claims 44-52 and 54-60, as well as for the features that they recite individually.

It should be noted that the applicant has not addressed each rejection of the dependent claims. Any rejection of a dependent claim not specifically addressed is not to be construed as an admission by the application of the correctness of that rejection. Rather, the applicant believes that the independent claims are patentably distinguishable over the cited references for the reasons noted above, so that the rejection of the dependent claims need not be addressed at this time. Applicant reserves the right to address the rejection of any dependent claim at a later time should that become warranted.

Claim 61

The rejection of claim 61 based on the proposed combination of the '801 patent and Kribbs should be withdrawn at least because the Examiner has not demonstrated that the cited references teach or suggest all of the features of the claimed invention.

For example, claim 61 recites *inter alia* the following features which are not taught or suggested by the sections of the '801 patent and/or Kribbs relied on in the Office Action:

> ...determining an actual medical device usage value for the compliance period by summing the measurements of medical device usage for each medical device usage session that is greater than or equal to the minimum medical device usage short session value and excluding from the sum each measurement of actual medical device usage value during a medical device usage session during the compliance period that is less than the minimum medical device usage short session value.

The Examiner acknowledges that the '801 patent does not teach the features of claim 61 reproduced above[p. 29]. The Examiner alleges that Kribbs addresses this deficiency of the '801 patent at FIG. 3 and page 889 [*id.*]. In particular, the Examiner alleges that in FIG. 3 (reproduced below), the "black squares" shown teach the "the measurements of medical device usage for each medical device usage session that is greater than or equal to the minimum medical device usage short session value," and that the "blank areas" shown teach "measurement of actual medical device usage value during a medical device usage session during the compliance period that is less than the minimum medical device usage short session value" [p. 29]. As Applicant set forth above with respect to claim 36 (which recites similar features), even if this application of Kribbs to the above-reproduced features of claim 61 is accepted (Applicant

contends that this interpretation of Kribbs is erroneous), the cited sections of Kribbs still do not teach the features of claim 61 reproduced above.

For the reasons presented above, Applicant respectfully submits that independent claim 61 is not rendered obvious by the cited references. Accordingly, Applicant respectfully requests that the above rejection of claim 36 be withdrawn.

Claims 62-64

The rejections of claims 62-64 based on the proposed combinations of the '801 patent, the '003 patent, the '717 patent, and/or the '513 patent should be withdrawn at least because the Examiner has not demonstrated that the cited references teach or suggest all of the features of the claimed invention.

For example, independent claim 62 recites *inter alia* the following features which are not taught or suggested by the sections of the '801 patent, the '003 patent, and/or the '717 patent relied on in the Office Action:

> ...(1) applying a weighting factor to each actual medical device session usage value to produce a weighted actual medical device session usage value for each medical device usage session, and (2) determining an actual medical device usage value for the compliance period by summing the weighted actual medical device usage values for the medical device usage sessions during the compliance period.

The Examiner acknowledges that the '801 patent does not teach or suggest these features, but relies on a combination of the '003 patent and the '717 patent as allegedly addressing this deficiency of the '801 patent. As Applicant set forth above with respect to the features of claim 37 (which are similar to the above-reproduced features of claim 62), the proposed combination of the '003 patent and the '717 patent does not teach or suggest "(1) applying a weighting factor to each actual medical device session usage value to produce a weighted actual medical device session usage value for each medical device usage session, and (2) determining an actual medical device usage value for the compliance period by summing the weighted actual medical device usage values for the medical device usage sessions during the compliance period."

For the reasons presented above, applicant respectfully submits that independent claim 62 is not rendered obvious by the cited references. The sections of the '513 patent cited in the Office Action do not address the deficiencies of the '801 patent, the '003 patent, and the '717 patent set forth above. As such, claims 63 and 64 are also not rendered obvious due to their dependency from independent claim 62. Accordingly, applicant respectfully requests that the above rejections of claims 62-64 be withdrawn.

It should be noted that the applicant has not addressed each rejection of the dependent claims. Any rejection of a dependent claim not specifically addressed is not to be construed as an admission by the application of the correctness of that rejection. Rather, the applicant believes that the independent claims are patentably distinguishable over the cited references for the reasons noted above, so that the rejection of the dependent claims need not be addressed at this time. Applicant reserves the right to address the rejection of any dependent claim at a later time should that become warranted.

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Claims 25 and 26 have been cancelled, thereby rendering their rejection moot. It is to be understood that these claims are being cancelled to facilitate the allowance of the remaining claims. The cancellation of these claims is not to be construed as an admission as to the correctness of the rejections of these claims. On the contrary, the application reserves the right to prosecute claims 25 and 26, or claims of similar scope, in a further continuing application.

No additional claim fees are believed to be required as a result of the above amendments to the claims. Nevertheless, the Commission is authorized to charge any fee required under 37 C.F.R. §§ 1.16 or 1.17 to deposit account no. 14-1270.

All objections and rejections have been addressed. It is respectfully submitted that the present application is in condition for allowance and a Notice to the effect is earnestly solicited.

Respectfully submitted,

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Note: The Commissioner is authorized to charge any fee required under 37 C.F.R. §§ 1.16 or 1.17 to deposit account no. 14-1270.